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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,687	08/19/2003	Haim Aviv	87754-7500	6729

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WASHINGTON, DC 20006

EXAMINER
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SOLOLA, TAOFIQ A

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 04/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/644,687	<b>Applicant(s)</b> AVIV ET AL	
	<b>Examiner</b> Taofiq A. Solola	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on 09 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☐ Claim(s) 1-6 and 8-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-6 and 8-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>2</u> . | 6) <input type="checkbox"/> Other: _____  |

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Claims 1-6, 8-24 are pending in this application.

Claim 7 is cancelled.

***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10, 15-16, 18-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Kloog et al., US 5,284,867.

Kloog et al., disclose the instantly claimed compound (HU-211), essentially free of the (3R,4R) enantiomer, various pharmaceutical formulations (compositions) for various types of administrations (columns 4-5) and methods of use for treating neurological disorders. The formulation is emulphor or emulsions and may contain antioxidants, preferably the antioxidant is  $\alpha$ -tocopherol. See example 3, column 12 and column 13, lines 1-5. Kloog et al., also disclose various % combinations of the emulsions in column 13, lines 5 to 23.

Applicant should note that the phraseology "essentially free of the (3R,4R) enantiomer" is deemed (3S,4S) enantiomer is in enantiomeric excess of at least 99.90 % over the (3R,4R) enantiomer absent a showing to the contrary.

Applicant's arguments filed 3/9/05 have been fully considered but they are not persuasive. Applicant submitted a declaration by Raphael Mechoulam asserting that the compound of the prior art is not 99.90 % enantiomeric pure. This is not persuasive because the assertion is not supported by a conclusive evidence.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kloog et al., US 5,284,867.

Applicant claims the (3S,4S) enantiomer of compound I having enantiomeric excess of at least 99.90 % over the (3R,4R) enantiomer, the composition and method of use for treating various neurological disorders. The composition comprise co solvents such as polyoxyl 35 castor oil from 30-80 % W/W, ethanol from 20-70 % W/W and 0.001-0.1 % w/w of edetic acid. Applicant also claims composition having 0.1-5 % W/W of  $\alpha$ -tocopherol.

Determination of the scope and content of the prior art (MPEP  $\S$ 2141.01)

Kloog et al., teach the instantly claimed compound (HU-211), essentially free of the (3R,4R) enantiomer, various pharmaceutical formulations (compositions) for various types of administrations (columns 4-5) and methods of use for treating neurological disorders. The composition comprise co solvents such as ethanol, glycerol, PEG and PPG. Kloog et al., also teach composition having 0.02 % W/W of  $\alpha$ -tocopherol. See columns 12-13.

Ascertainment of the difference between the prior art and the claims (MPEP  $\S$ 2141.02)

The difference between the instant invention and that of Kloog et al., is that applicant claims the instant compound having (3S,4S) enantiomeric excess of at least 99.90 % over the (3R,4R) enantiomer, while Kloog et al., teach the compound as essentially free of the (3R,4R) enantiomer. Also, applicant is claiming co solvents such as polyoxyl 35 castor oil from 30-80 % W/W, ethanol from 20-70 % W/W and 0.001-0.1 % W/W of edetic acid, while Kloog et al., do not teach polyoxyl 35 castor oil, edetic acid or % W/W of ethanol.

Finding of prima facie obviousness---rational and motivation (MPEP  $\S$ 2142.2413)

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However, there is no evidence that the compound of Kloog et al., does not have (3S,4S) enantiomeric excess of at least 99.90 % over the (3R,4R) enantiomer. Even if the instantly claimed compound is substantially purer than the compound of Kloog et al., and there are new and novel properties, functions or utilities arising from the higher level of purity, such would not make the instant invention patentable over the prior art of Kloog et al. Something old does not become new upon discovery of new properties (e.g. purification level), functions or utilities. *In re Best*, 562 F.2d 1252; 195 USPQ 430 (CCPA, 1977). Also, the addition of an inert carrier, such as co-solvents, to a non-patentable compound is not patentable. *Ibid*. Claiming 20-70 % ethanol and 0.1-5 %  $\alpha$ -tocopherol are obvious modifications available to the special preference of an artisan. They are mere optimization of variables, which are not patentable absent unexpected result due to each variable, which is different in kind and not merely in degree from that of the prior art. *In re Aller*, 22 F.2d 454, 105 USPQ 233 (CCPA, 1955).

Therefore, the instant invention is prima facie obvious from the teaching of Kloog et al. One of ordinary skill in the art would have known to claim compound of formula I as (3S,4S) enantiomeric excess of at least 99.90 % over the (3R,4R) enantiomer at the time this invention was made. The motivation is from the teaching of Kloog et al., that the compound is essentially free of the (3R,4R) enantiomer.

Applicant's arguments filed 3/9/05 have been fully considered but they are not persuasive. Applicant asserts that while the instant compound is at least 99.90 % enantiomeric pure, the compound of the prior art is not as pure. This is not persuasive for reasons set forth above under 35 USC 103. Applicant also contends the higher purity of the instant compound is a very crucial need. While the Examiner does not want to discount applicant's effort, changing the enantiomeric ratio of a known compound does not rise to the level of invention under US patent practice as set forth above under 35 USC 103.

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***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD, JD, whose telephone number is (571) 272-0709.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph McKane, can be reached on (571) 272-0699. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

  
**TAOFIQ SOLOLA**  
**PRIMARY EXAMINER**  
Group 1626

April 18, 2005